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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,806	11/02/1999	UWE VINKEMEIER	600-1-182NA	7760

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EXAMINER	
LACOURCIERE, KAREN A	

ART UNIT	PAPER NUMBER
1635	11

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/430,806	Applicant(s) VINKEMEIER ET AL.
	Examiner Karen A. Lacourciere	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2002*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 56-79* is/are pending in the application.

4a) Of the above claim(s) *1,60 and 61* is/are withdrawn from consideration.

5)☒ Claim(s) *56-59,76 and 77* is/are allowed.

6)☒ Claim(s) *62-75,78 and 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4)☐ Interview Summary (PTO-413) Paper No(s). _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

FILE COPY

DETAILED ACTION

Election/Restriction

This application contains claims 1, 60 and 61 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 62-75, 78 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 62 and claims dependent on claim 62 are indefinite due to the recitation "said second protein dimer" in line 4 of the claim. The term "said second protein dimer" lacks antecedent basis.

Claim 66 and claims dependent on claim 66 are indefinite due to the recitation "whereas" at the beginning of line 11 of the claim. The word "whereas" is grammatically incorrect.

Amending the claim to replace the word "whereas" with the word "wherein" would obviate this rejection.

Claim 70 and claims dependent on claim 70 are indefinite due to the recitation "said second protein dimer" bridging lines 3 and 4 of the claim. The term "said second protein dimer" lacks antecedent basis.

Claim 70 and claims dependent on claim 70 are indefinite due to the recitation "whereas" at the beginning of line 11 of the claim. The word "whereas" is grammatically incorrect. Amending the claim to replace the word "whereas" with the word "wherein" would obviate this rejection.

Claim Rejections - 35 USC § 102

The rejection of record of claims 56 and 59, as anticipated by McKnight et al. is withdrawn, in response to applicant's amendments, filed 03-01-02.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 66-75 are rejected under 35 U.S.C. 102(e) as being anticipated by McKnight et al. (reference AC on PTO form 1449, US Patent No 5,710,266).

McKnight et al. disclose an assay to determine drugs which inhibit the dimerization of IL-4 STAT protein, which corresponds to STAT6,(see for example column 4-5). Therefore, McKnight et al. anticipates claims 66-75.

Claims 66-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Leonard (US Patent No 6,265,160).

Leonard disclose assays to determine drugs which interfere with the activity of STAT3 and STAT5 proteins. Leonard et disclose these assays as determining agents (e.g. peptides) which interfere with the dimerization or heterodimerization of STAT3 or STAT5 proteins (see for example column 13-14). Therefore, Leonard anticipates claims 66-73.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 66-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard in view of Xu et al. (reference BB on PTO form 1449) further in view of Schreiber et al.

Claims 66-75 are drawn to methods of identifying a drug which inhibits the ability of adjacent STAT dimers to interact wherein compounds are tested for their ability to modulate the interaction of a polypeptide which consists essentially of the amino terminal domain of a STAT polypeptide with a second STAT polypeptide comprising the amino terminal domain of said second STAT protein. Specific embodiments include identifying drugs which interfere with the interaction of STAT1, STAT2, STAT3, STAT4, STAT5A, STAT5B or STAT6 and wherein the interaction is heterodimerization or homodimerization.

Leonard teaches assays to identify drugs which inhibit the activity of STAT proteins, including STAT3 and STAT5 and further teach assays which interfere with the homodimerization or heterodimerization of STAT proteins (see for example column 13-14).

Leonard does not teach assays to identify drugs which interfere with the homodimerization or heterodimerization of STAT proteins wherein one STAT protein consists essentially of the amino terminal domain of said STAT protein. Further, Leonard does not teach assays to identify inhibitors of STAT1, STAT2 or STAT4 homodimerization or heterodimerization.

Schreiber et al. teaches assays which identify drugs which interfere with the transcriptional activation of STAT protein family members, including STAT 1, STAT2, STAT3, STAT4 and STAT5.

Xu et al. teach that the amino terminal domain of STAT protein family members is essential for dimerization and cooperative DNA binding.

It would have been obvious to one of ordinary skill in the art to assay for drugs which inhibit the heterodimerization or homodimerization of STAT1, STAT2, STAT3, STAT4 or STAT5 because Leonard teach identifying drugs which interfere with the heterodimerization or homodimerization of STAT proteins, specifically STAT3 and STAT5, interfere with transcriptional activation of STAT proteins and Schreiber et al. teach identifying drugs which modulate the transcriptional activation of STAT proteins, including STAT1, STAT2, STAT3, STAT4 and STAT5 and Xu et al. teach that heterodimerization or homodimerization of STAT proteins is important for transcriptional activation of said proteins. It would have been further obvious to perform the assays identifying drugs which modulate the heterodimerization or homodimerization of these STAT proteins using the amino terminal domain of one of the STAT proteins because Xu et al. identify the amino terminal domain of STAT proteins as the domain

essential for heterodimerization or homodimerization. One skilled in the art would have been motivated to perform the assays taught by Leonard for other STAT proteins, including STAT1, STAT2, STAT3, STAT4 and STAT5, because Schreiber et al. teach drugs inhibiting STAT1, STAT2, STAT3, STAT4 and STAT5 are useful for the treatment of inflammatory and autoimmune diseases. One skilled in the art would be motivated to perform these assays using the amino terminal domain of said STAT proteins because Xu et al. teach that the amino terminal domain is the domain responsible for or homodimerization.

Therefore, at the time the instant invention was made, the inventions of claims 66-75 would have been obvious, as a whole, to one of ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 03-01-02 have been fully considered but they are not persuasive. In response to the rejections of record under 35 U.S.C. 102(e) and 103(a), Applicant argues that the cited references, Leonard et al. and McKnight et al. do not anticipate the claimed invention because the methods claimed are drawn to methods of determining drugs which inhibit or enhance the association of STAT dimers into higher order structures, whereas the cited references are directed to methods of determining drugs which interfere with the association of STAT proteins into dimers. Applicant provides a similar argument with respect to the rejection of record under 103(a), in that the cited references do not provide all of the limitations of the claimed methods because there is no teaching for interfering with dimer association. these

arguments have not been found to be persuasive because the methods recited by McKnight et al. and Leonard et al. recite methods which comprise the same steps as the claimed methods. The claimed methods recite dimer association only within the preamble, however, this has not been given patentable weight because the steps of the claimed methods are identical to those disclosed in the cited prior art.

Conclusion

Any rejection of record not repeated herein is considered to be withdrawn.

Claims 56-59, 76 and 77 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday to Fridays from 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ANDREW WANG
PRIMARY EXAMINER

Karen A. Lacourciere

May 19, 2002